

REMARKS

Claims 40, 43, 44, 46, 48 and 59-64 were acted upon in the aforesaid Office Action. Claim 46 has previously been canceled and new claims 65 and 66 have been added, leaving claims 40, 43, 44, 48 and 59-66 for consideration.

Claims 40 and 48 and claims depending therefrom stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,280,478 - Richter et al., U.S. Patent No. 5,518,680 - Cima et al., and U.S. Patent No. 6,129,872 - Jang et al., "as evidenced by" U.S. Patent No. 5,549,679 - Kuslich.

Exhibits 1, 7 and 8 have been deemed darkly colored and uninterpretable. Copies of those exhibits are submitted herewith and, hopefully, are of better quality than those previously reaching the Examiner. The applicant requests that the Examiner review the exhibits in view of the comments provided in response to the previous Office Action as submitted on 9 January 2009.

Objection Under 35 U.S.C. §103

The Examiner has held that claims 40, 43, 44, 48, 50, 51, and 56-64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (US 6,280,478) (hereinafter referred to as "the '478 patent"), Cima et al (US 5,518,680) (hereinafter referred to as "the '680 patent"), and Jang et al (US 6,129,872) (hereinafter referred to as "the '872 patent"), as evidenced by Kuslich (US 5,549,679) (hereinafter referred to as "the '679 patent").

Claims 50 and 51 have previously been canceled, leaving claims 40, 43, 44, 48 and 56-64 as rejected under the aforesaid combination of references.

Turning to the combination of prior art references, it appears that the Jang reference pertains to the field of creating colorful three-dimensional objects by depositing of layers which individually are of one color, or alternatively, to provide layer upon layer, wherein each layer may exhibit more than one color.

It appears that Jang is taken from a non-analogous art. While a wide spectrum of prior art is rightly considered in questions of analogous arts, it is believed that the general rule is that the prior art must be that to which one would normally turn to find a solution to a problem. It is submitted that one in the medical field seeking to improve upon the building of cell growth encouraging structures would not be expected to turn to the art of manufacturing colorful objects for aid in, or for ideas in, the cell growth area of medicine.

It is not understood how U.S. Patent No. 5,549,679 - Kuslich "evidences" the combination of Richter, Cima and Jang. Kuslich appears to relate to a method for using a spinal implant which is essentially inserting a bag into an annulum of a disc and filling the bag with bone growth material, causing the bag to expand.

It is believed, therefore that to the extent of the prior rejections being based in part on these two references, such rejections are inappropriate, and should be rescinded.

The Examiner on page 5 of the Office Action has acknowledged that the difference between the present invention and the prior art is the lay-down pattern (i.e. shape) of the melt extrusion filament used to construct the scaffold apparatus. The Examiner goes on to say that the '478, '680 and '872 patents clearly teach that this pattern can be varied, depending on the design and structural needs of the maker, and that the variations in pattern

lay-down are known variations of the prior art. The Examiner is also of the opinion that these would have been readily predictable to one of skill in the art at the time the invention was made.

The applicant respectfully disagrees with the Examiner. As submitted in the previous response filed on 9 January 2009, although the '478, '680 and '872 patents teach that the pattern can be varied, and although (as the Examiner states) the '478 patent teaches that the components can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component, the present invention is a selection invention in which the specific lay-down patterns of 0°/60°/120° and 0°/77°/144°/36°/108° are claimed in each of claims 40 and 48, respectively.

In particular, the applicant would like to bring to the Examiner's attention MPEP 2144.08 (II), which states that the fact that a claimed species or subgenus is encompassed by a prior art generic formula does not itself render that compound obvious (*In re Baird*, 16 F.3d 380, 382; 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). By applying this principle to the present invention, since there is no suggestion of the specific lay-down patterns as recited in claims 40 and 48 in any one of the cited documents, claims 40 and 48 should not be deemed obvious in view of the cited documents.

Further, if the Examiner's obviousness assertions that the specific lay-down patterns as recited in claims 40 and 48 are indeed predictable by a person of skill in the art, apparatus for use in tissue engineering having lay-down patterns of 0°/60°/120° and 0°/77°/144°/36°/108°, as recited in claims 40 and 48, respectively, would have been disclosed before the present

invention was made, especially given the advantages provided by the apparatus. The advantages provided by the apparatus of claims 40 and 48 can be derived from the experimental results provided in the examples of the present application, as well as in each of Exhibits 2 to 5 (previously submitted together with the response filed with the USPTO on 9 January 2009).

In view of the above, the applicant submits that claims 40 and 48, and their dependent claims, are not obvious over the '478, '680, '872 and '679 patents. In particular, a person of skill in the art referring to the above-mentioned patents, whether individually or in combination, would not be motivated to arrive at the specific lay-down patterns as recited in claims 40 and 48 since none of the cited patents even suggests or offers the advantages demonstrated by the apparatus of claims 40 and 48.

For the reasons provided above, the applicant submits that new claims 65 and 66 are also patentable.

Objection under 35 U.S.C. §112

The Examiner is of the opinion that the pore size range of 200-780 μm , as recited in claims 40 and 48, is not taught in the specification. In particular, the Examiner at page 6, paragraph 12, of the Office Action states that a range of 200-700 μm is taught at page 40 of the specification of the present application while a range of 250-780 μm is recited in Table 1 at page 36 of the specification.

The applicant submits that the recited pore size range does not constitute new matter since each of the end limits of the range 200-780 μm have been disclosed in the application as originally filed. Further, it can be derived from MPEP 2163.05 (III) that since claims 40 and 48 do not read literally on

embodiments outside a range disclosed by the application as originally filed, the range meets the description requirement. Accordingly, contrary to the Examiner's view, it is not a requirement that the presently claimed pore size range be specifically disclosed in the specification as originally filed.

Therefore, the range 200-780 μm does not constitute new matter since it has been disclosed in the written description.

Objection under 35 U.S.C. §102

The Examiner is of the opinion that claims 40, 43, 59 and 60 are anticipated by Hutmacher et al, "Design and Fabrication of a 3D Scaffold for Tissue Engineering Bone", as published in Agrawal et al, Eds Synthetic Bioadsorbable Polymers for Implants, ASTM, West Conchohocken, PA; May 2000, pp.152-167 (hereinafter referred to as "Hutmacher").

Three of the authors in Hutmacher, namely Swee Hin Teoh, Dietmar W. Hutmacher and Iwan Zein are named as inventors in respect of the present application. Further, the effective filing date of the present application is 20 September 2000 (i.e. the filing date of the provisional application from which the present application claims benefit under 35 U.S.C. 119(e)), which is within one year from the date of publication of Hutmacher. Accordingly, the applicant submits that Hutmacher should not be considered as prior art against the present application.

- 13 -

In the event that any fees may be required in this matter,
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Respectfully,



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